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September 22, 2006

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Andrew C. von Eschenbach, M.D.
Acting Commissioner
U.S. Food and Drug Administration
U.S. Department of Health and Human Services
5600 Fishers Lane, Room 15-47
Rockville, MD 20857

Dear Dr. von Eschenbach:

As of September 21, 2006, 157 persons in 23 states have been infected with E. coli 0157:H7 in an outbreak traced back to fresh spinach. The infection has been severe in affected cases, with at least 83 persons hospitalized, 27 cases of hemolytic uremic syndrome, and at least one death.¹

This is not the first, or even the second or third, such outbreak. Since 1995, there have been 20 separate outbreaks of E. coli in fresh produce, accounting for 409 reported cases of illness and two deaths.² An outbreak in October of 2003 was specifically linked to fresh spinach.³

Despite the repeated occurrence of these outbreaks, I am concerned that FDA has not conducted adequate inspections of the plants that process spinach and other produce. In 2003, FDA's Deputy Commissioner testified before Congress that the agency planned to conduct just "one inspection every five years for most domestic food producing facilities."⁴ Other accounts report that FDA's inspections may be even less frequent. According to a former FDA associate commissioner, food inspections have dropped from 50,000 in 1972, to about 5,000 today, or about one inspection every ten years for our nation's 65,000 food firms.⁵ In fact, FDA budget

¹ Centers for Disease Control, *Update on multi-state outbreak of E. coli O157:H7 infections from fresh spinach, September 21, 2006* (online at <http://www.cdc.gov/foodborne/ecolispinach/current.htm>) (accessed September 22, 2006).

² U.S. Food and Drug Administration, *Letter to California firms that grow, pack, process, or ship fresh and fresh-cut lettuce* (November 4, 2005).

³ U.S. Food and Drug Administration, *Nationwide E. Coli O157:H7 outbreak: questions and answers* (online at <http://www.cfsan.fda.gov/~dms/spinacqa.html>) (accessed September 20, 2006).

⁴ Lester M. Crawford, Deputy Commissioner, Food and Drug Administration, Testimony before the Senate Committee on Homeland Security and Governmental Affairs, (November 19, 2003).

⁵ William Hubbard, *Wrongly blaming the FDA*, Washington Post (May 8, 2006).

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materials project that this rate will drop even further, falling from 4,573 inspections in fiscal year 2005 to about 3,400 in 2006.⁶

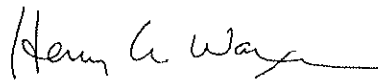
In a briefing yesterday, FDA officials stated that most high risk firms, including those producing fresh leafy greens, are inspected annually.⁷ However, the officials could not say how thorough these inspections were or whether they included testing of produce for contamination. Moreover, an annual inspection rate is still far below the degree of food safety oversight conducted by the Department of Agriculture, which inspects meat and poultry processing facilities on a daily basis.⁸

In order to evaluate the steps taken by FDA to oversee fresh produce safety, I request that you provide the following information:

1. Documentation of the inspection history since January 2001 for domestic firms producing packaged fresh spinach, including all records relevant to the firms that have been associated with the current outbreak. Such records should include the dates of inspection, inspection findings, and enforcement actions taken as a result of the findings;
2. Documentation of any enforcement actions recommended by FDA staff but ultimately not taken against firms producing packaged fresh spinach since January 2001. Please include documentation of FDA's reasons for disapproving such recommendations;
3. Documentation of the inspection history since January 2001 for domestic firms producing packaged fresh produce other than spinach, including dates of inspection, inspection findings, and enforcement actions taken as a result of the findings.

Given the urgency of the current situation, I ask that you provide the information identified in requests one and two by October 4 and the information identified in request three by October 18. Please contact Stephen Cha at (202)225-5420 if you have any questions regarding this request.

Sincerely,



Henry A. Waxman
Ranking Minority Member

⁶ US House of Representatives Agriculture Appropriations Subcommittee hearing, (February 16, 2006).

⁷ Briefing by staff of the Centers for Disease Control and Prevention and the Food and Drug Administration to House Government Reform Committee Staff (Sept. 21, 2006).

⁸ 9 C.F.R. §§ 309, 310.